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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,414	09/25/2001	Fumiyasu Hirai	12218/1	6930

7590 08/16/2004  
KENYON & KENYON  
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1500 K Street, N.W.  
Washington, DC 20005

EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/961,414

Applicant(s)

HIRAI ET AL.

Examiner

Vanessa L. Ford

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.  
2. ☐ The proposed amendment(s) will not be entered because:  
(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ they raise the issue of new matter (see Note below);  
(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): Rejection of claim 4 and 6-9 under 35 U.S.C. 102(b).  
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see Advisory Attachment.  
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.  
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.Claim(s) objected to: NONE.Claim(s) rejected: 4 and 6-10.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.  
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.  
10. ☒ Other: Advisory Attachment

**ADVISORY ATTACHMENT**

1. This Office Action is responsive to Applicant's response filed June 21, 2004.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

***Objection Withdrawn***

3. In view of Applicant's response the rejection of claims 4 and 6-9 under 35 U.S.C. 102(b) pages 2-4, paragraph 4 is withdrawn.

***Rejection Maintained***

4. The rejection of claims 4 and 6-10 under 35 U.S.C. 103(a) as unpatentable over Nagaki et al in view of Hirai et al is maintained for the reasons set forth on pages 4-6, paragraph 5 of the previous Office Action.

The rejection was on the grounds that Nagaki et al teach a method for adsorptive removal of enterotoxin A from plasma of rats using various adsorbents (see the Title and the Abstract). Nagaki et al disclose a study that evaluates the capacity of various adsorbents to bind enterotoxin A and directly remove the toxin from the circulation (page 354, 2nd column). Nagaki et al teach that the direct removal of enterotoxins from the circulation may be of potential therapeutic value in preventing the consequences of staphylococcal septicemia (page 354, 2<sup>nd</sup> column).

Nagaki et al do not teach the use of an adsorbent comprising a compound with a log P in which P represents a partition coefficient in an octanol-water system value of not less than 2.50 as immobilized on a water-insoluble carrier.

Hirai et al teach an adsorbent comprising a compound which has a log P value of at least 2.50 wherein P is a partition coefficient in an octanol-water system and which is immobilized on a water-insoluble carrier used to eliminate toxins from body fluids by adsorption (see the Abstract). Hirai et al teach that the

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water-insoluble carrier is a porous carrier which has an exclusion limit for globular protein of 10,000 to 600,000 (page 5, paragraphs 0033 and 0034).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to add the adsorbent as taught by Hirai et al to the adsorbents used in the method for adsorptive removal of enterotoxin A from plasma of Nagaki et al because Hirai et al teach that the adsorbents comprising compound which has a log P value of at least 2.50 can be used alone or in combination with compounds that have a log P value of less than 2.50 to remove toxins (page 4, paragraph 0027). It would be expected barring evidence to the contrary that the addition of the adsorbents as taught by Hirai et al to the adsorbents used in a method of removing enterotoxins from body fluids of Nagaki et al can be effective in removing enterotoxins from body fluids because Hirai et al have demonstrated that the adsorbents comprising compound which has a log P value of at least 2.50 can be used to remove toxins (i.e. toxic shock syndrome toxin -1 (TSST-1)) which is a toxin released by *Staphylococcus aureus* that is structurally closely related to enterotoxins (Nagaki et al, page 354, 1<sup>st</sup> column). Additionally, the exclusion limit as described by Hirai et al for the removal of TSST-1 is within the range of the exclusion limit for the removal of the claimed staphylococcal enterotoxins.

Applicant urges that Nagaki et al do not provide a teaching of enterotoxins. Applicant urges that Nagaki et al teach a method for adsorbing TSST-1. Applicant urges that Nagaki et al merely describes that enterotoxins and TSST-1 are structurally related and does not teach or suggest that TSST-1 and enterotoxins have the similar adsorption properties. Applicant urges that there is no reasonable expectation that the combination of references would be successful in arriving at the claimed invention. Applicant urges that there is no motivation to combine the teachings of Nagaki et al with the teachings of Hirai et al.

Applicant's arguments filed June 21, 2004 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness

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can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Nagaki et al teach a method of removing enterotoxins using adsorbents and Hirai et al teach that TSST-1 can be removed using compounds that have a P value of at least 2.50, most preferably 2.80 or more and more preferably 3.0 or more (page 3). It would be obvious to use the compounds as taught by Hirai et al in the method of removing enterotoxins as taught by Nagaki et al because Hirai et al teach that adsorbents comprising compounds such as isocyanates, amines, alcohols, halides, aldehydes, hydrazides, carboxylic acids and derivatives thereof, thiols and unsaturated hydrocarbons, silanes (which have log P values of not less than 3.00) can be used to remove TSST-1 which is structurally similar to enterotoxins (page 4). Hirai et al specifically teach that amines such as hexadecylamine can be used in the method of removing TSST-1 (page 4). It should be noted that the adsorbent comprising compounds with log P values of not less than 3.00 as immobilized on a water-insoluble carrier used for the removal of TSST-1 as taught by Hirai et al are the same as the adsorbents used in the claimed method of removing enterotoxins (see page 7 of the instant specification). Therefore, one of skill in the art would reasonably conclude that TSST-1 (an exotoxin) and enterotoxins have similar adsorbent properties and TSST-1 as well as

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enterotoxins can be removed using an adsorbent comprising a compound with a log P value of not less than 3.00 as immobilized on a water-insoluble carrier with a reasonable expectation of success. Therefore, there is nothing on the record to teach or suggest that the combination of references do not teach the claimed method.

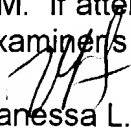
### ***Status of Claims***

5. No claims allowed.

6. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

  
Vanessa L. Ford  
Biotechnology Patent Examiner  
August 1, 2004

  
NITA MINNIFIELD  
PRIMARY EXAMINER